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| 10/791,974 | 03/03/2004 | Ray L. Pickup | 10004227-9 | 4848 |

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HEWLETT-PACKARD COMPANY
Intellectual Property Administration
P.O. Box 272400
Fort Collins, CO 80527-2400

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| EXAMINER |
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HAND, MELANIE JO

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| ART UNIT | PAPER NUMBER |
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3761

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 02/05/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/791,974

Applicant(s)

PICKUP ET AL. C

Examiner

Melanie J. Hand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 83-100, 102, 118-120, 123-128, 131-133, 136, 140, 141 and 148-150 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 83-100, 102, 118-120, 123-128, 131-133, 136, 140, 141 and 148-150 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments, see Remarks, pages 12,13, filed November 13, 2006, with respect to the rejection of claim 83 under 35 U.S.C. 112 have been fully considered and are persuasive. The rejection has been withdrawn.

Applicant's arguments filed with respect to the rejection of claims 83-100,102-120,123-133, 136, 140, 141 and 148-150 have been fully considered but they are not persuasive.

With respect to applicant's arguments regarding the prior art of Jacobsen: Applicant argues that Jacobsen does not teach the step of retaining the bioactive composition in prolonged contact with the cutaneous surface. Applicant also argues that Jacobsen teaches needle-less and needle-based injection systems, and such systems do not involve retaining a bioactive composition in prolonged contact with the cutaneous surface. Examiner disagrees. Jacobsen explicitly teaches a drug delivery apparatus that is held on a patient's skin surface for single or multiple dosages and is intended for use by patients who lack the skill or time or who are physically challenged. (Col. 4, lines 49-61) Thus the device is intended for wear over a prolonged time period on the skin surface and thus retains the drug dispenser and drug held therein in prolonged contact with the cutaneous surface. Applicant argues, citing Figures 5 and 8 of Jacobsen, that Jacobsen teaches a single event dosage using a stream of liquid. Examiner refers applicant to Figure 7 and Col. 11, lines 6-40 which contain a description of the embodiment of Fig. 7 which is a fluid jet drug delivery device in which the drug is administered using a propellant through a nozzle, which is clearly not a single event dosage using a stream. Examiner has restated the rejection to refer primarily to Figure 7 for clarity.

With respect to applicant's arguments regarding the prior art of Crivelli: Applicant argues that Crivelli does not teach or suggest any type of cutaneous delivery. This is correct, however one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The prior art of Jacobsen already addresses cutaneous delivery. Further, the prior art of Crivelli was introduced to remedy the deficiency of Jacobsen with respect to droplet volume. The rejection is over the combined teaching of Jacobsen and Crivelli. Applicant further argues that there is no motivation to combine these references because Crivelli teaches an ink jet dispenser. Examiner has stated in the previous Office action that because Jacobsen teaches a jet dispenser, albeit for drug delivery, Jacobsen is teaching that such a structure can be used for drug delivery, hence one of ordinary skill in the art would be motivated to look to the ink jet dispenser art for structural features for a similarly structured drug jet dispenser. Thus, while Crivelli does not teach a device that is used for cutaneous delivery of a drug, since the structure of an ink jet dispenser as taught by Crivelli and a drug jet dispenser as taught by Jacobsen are at least analogous if not substantially identical and seek to solve a similar problem (i.e. delivering a substance to a surface in a fluid jet form), there exists motivation to combine the drug jet dispenser taught by Jacobsen with the ink jet dispenser taught by Crivelli.

Applicant's arguments with respect to claim 91 are addressed supra as applicant's arguments regarding the rejection of claim 91 are based upon arguments made with respect to the rejection of claim 83.

With respect to applicant's arguments regarding the prior art of Hayes: Applicant argues that the prior art devices of Crivelli and Hayes have contradictory goals and thus there is no motivation to combine. While it is correct that the device of Hayes creates aerosols as a by-

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product of creating a stream of droplets for inhalation via a user's nose, such creation of aerosols does not contradict the goal of the device of Crivelli. The device of Crivelli creates aerosols as well, as such creation is an inevitable by-product of propellants during use. Crivelli teaches that smaller droplets require less aerosols, however less aerosol production is not equivalent to no aerosol production, and thus the goal of the device of Crivelli, i.e. to deliver a jet stream of droplets of a substance to a surface, is not contradictory to the goal of the device of Hayes. In fact the goals or problems to be solved by the two devices are very similar. Thus it would be obvious to combine the devices of the combined teaching of Jacobsen and Crivelli with the device of Hayes.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 83-100, 108, 109, 119, 120, 123, 126-128, 140, 141, and 148-150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (U.S. Patent No. 5,860,957) in view of Crivelli (U.S. Patent Application Publication No. 2003/0016262).

With respect to **Claim 83**: Jacobsen teaches a method of administering a bioactive composition to a subject, the method comprising: applying to a cutaneous surface of the subject a jet dispenser 450 (Fig. 7) comprising a container 300 holding the bioactive composition (Col. 11, lines 6-8, 17-20); dispensing the bioactive composition in droplets from the dispenser through at least one orifice in nozzle 460 toward the cutaneous surface (Col. 11, lines 10-20); and retaining

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the bioactive composition in prolonged contact with the cutaneous surface. (Figs. 1,7, Col. 11, lines 10-20)

With respect to **claim 84**: Retaining the bioactive composition in prolonged contact with the cutaneous surface comprises dispensing the bioactive composition on to a dermal patch 20 that is retained on the cutaneous surface. (Fig. 1, Col. 5, lines 12-19)

With respect to **claim 85**: The dermal patch 20 is an adhesive dermal patch that is applied to the cutaneous surface prior to dispensing the bioactive composition from the dispenser 450. (Col.5, lines 50-54)

With respect to **claim 86**: The dermal patch 20 comprises a selectively removable cover that is removed prior to dispensing the bioactive composition into the patch, and is subsequently replaced on the patch to improve retention of the bioactive composition in the patch. (Col. 5, lines 54-61)

With respect to **claim 87**: Retaining the bioactive composition in prolonged contact with the cutaneous surface comprises providing a seal 360 between the dispenser and cutaneous surface, to form a substantially sealed chamber (as seen in Fig. 7 between the jet nozzle and chamber 300) between the dispenser and the cutaneous surface, and retaining the dispenser in prolonged contact with the seal 360. (Col. 10, lines 13-15)

With respect to **claim 88**: The method taught by Jacobsen further comprises repeatedly dispensing the bioactive composition toward the cutaneous surface. (Col. 4, lines 46-48)

With respect to **claim 89**: The method taught by Jacobsen further comprises resupplying the dispenser 450 with the bioactive substance in order to administer multiple drugs and/or dosages. (Col. 4, lines 45-49)

With respect to **claim 90**: Resupplying the dispenser comprises replacing a container 300 in the dispenser.

With respect to **claim 91**: Jacobsen teaches a method of administering a bioactive composition to a subject, the method comprising: applying a cutaneous patch 20 to skin of the subject (Col. 5, lines 12-19); and dispensing the bioactive composition from an inkjet dispenser 450 by ejection through an orifice 460 to the patch 20. (Col. 5, lines 12-19)

With respect to **Claims 92,93**: Jacobsen teaches that control pad 10 allows the user to program various frequencies of drug delivery, including dosages that enabled sustained levels of a drug through a maintenance delivery sequence and dosages administered at intervals. (Col. 5, lines 24-32, Col. 6, lines 45-50)

With respect to **Claim 94**: Jacobsen teaches that device 20 is capable of storing and mixing two separate drug composition components prior to delivery to a cutaneous surface. (Col. 13, lines 54-62)

With respect to **Claims 95,96**: Jacobsen teaches pod 580 having a first chamber 582 that is half full of a first drug component to be mixed with a second component. Said second drug

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component is stored in a second chamber 584 until it is ejected through a one-way valve 596 (interpreted herein as an orifice) to said first chamber 582 wherein it is mixed with said first component and the resulting composition is then capable of being delivered through patch 20. (Col. 13, lines 54-66, Col. 14, lines 1,2)

With respect to **Claim 97**: Since Jacobsen teaches that delivery device 20 is a patch and a drug delivery pod 580 capable of mixing two components of the same of different phases, Jacobsen is teaching that the component mixing is capable of occurring within a patch 20.

With respect to **Claims 98,148**: Jacobsen teaches administering a drug cutaneously via a multipathway drug delivery device 20 comprising a fluid jet delivery pod 510 and drug containment pouch 506. (Col. 11, lines 50-52) The drug is expelled through aperture 522. (Col. 12, lines 1-5) Jacobsen teaches that the device is capable of administering daily delivery of a drug composition (Col. 5, lines 27-29), therefore the device is intended for prolonged contact with a cutaneous surface and capable of repeatedly dispensing a drug composition.

With respect to **Claims 99,100,150**: The method taught by Jacobsen further comprises repeatedly dispensing the bioactive composition toward the cutaneous surface. (Col. 4, lines 46-48) The method taught by Jacobsen further comprises resupplying the dispenser 450 with the bioactive substance in order to administer multiple drugs and/or dosages. (Col. 4, lines 45-49)

With respect to **Claims 108,109,118,126**: Jacobsen teaches that a drug is specifically selected by name via the ability of device 20 to read a label on a drug storage container as it is inserted. An external host interface 48 obtains and stores data via a wireless infrared reading device from

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a computer having microprocessor 40, said data including user ID, drug ID, dose and usage information. Wireless interface 48 then uses said data to monitor a patient's physiological status in tandem with sensors, this circuit also thus being capable of responding to the data by administering the appropriate dosage via device 20 according to the stored schedule data. (Col. 7, lines 24-38)

With respect to **Claims 119, 120, 127, 128**: Please see the rejection of claim 108 in addition to the following: Jacobsen teaches using device 20 having interface 48 to administer stimulants, which would require monitoring of a patient's heartbeat and breathing (directly correlated to a change in activity level) as physiological parameters in order to function properly. (Col. 6, lines 32-35)

With respect to **Claims 123, 131**: Jacobsen teaches monitoring a physical parameter of a subject by using a monitor portion comprised of wireless interface 48 and sensors.

With respect to **Claims 140, 141**: Jacobsen teaches that control pad 10 is responsible for sending electrical current to ignition wiring, which then ignites propellant gas, which expands the drug containment pouch so as to propel the drug in a gaseous state as a stream of droplets through nozzle 460 for delivery into the user's skin. Control pad 10 comprises a keypad 42 that is adapted for receiving input in the form of keystrokes from a user, which defines a manual triggering of control pad 10, the actuation device.

With respect to **Claim 149**: Jacobsen teaches that device 20 has double-sided adhesion to prevent movement on a cutaneous surface after said patch 20 is applied, after which

application, said device 20 is operatively connected to control pad 10 by communication cable 30 which actuates a drug administration program. (Col. 5, lines 13-55) Device 20 is encased in a foil wrapper prior to use. This wrapper can be reused to cover patch 20 again after a drug has been delivered to the absorbent sponge material in the patch to retain any drug composition amount present in said sponge material. (Col. 5, lines 55-61)

Claims 102-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (U.S. Patent No. 5,860,957) in view of Crivelli (U.S. Patent Application Publication No. 2003/0016262) as applied to claims 83-100, 108, 109, 119, 120, 123, 126-128, 140, 141, and 148-150 above, and further in view of Hayes et al (U.S. Patent No. 6,325,475).

With respect to **Claims 102-107**: Jacobsen teaches a fluid jet dispenser 450 but does not teach a particular type of fluid jet dispenser. Hayes teaches a jet dispenser for administering airborne materials into a user's nose that utilizes ink-jet technology. Hayes teaches that the transducer in the ink jet device can be piezoelectric or electromechanical, which encompasses thermal and silicon electrostatic transducers. ('475, Col. 7, lines 29-37) Since Hayes teaches that these are equivalent and all are suitable for use in an inkjet drug delivery device, it would be obvious to one of ordinary skill in the art to utilize any of piezoelectric, thermal or silicon electrostatic transducers as taught by Hayes.

Claims 124, 125, 132 and 133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (U.S. Patent No. 5,860,957) in view of Crivelli (U.S. Patent Application Publication No. 2003/0016262) as applied to claims 83-100, 108, 109, 119, 120, 123, 126-128, 140, 141, and 148-150 above, and further in view of Meyerson et al (U.S. Patent No. 5,179,947).

With respect to **Claims 124,125,132,133**: Jacobsen teaches a plurality of sensors 60 for providing feedback regarding a patient's physiological status. Jacobsen does not teach any particular type of sensor. Meyerson teaches an acceleration-sensitive cardiac pacemaker that employs an accelerometer (mechanical sensor) to monitor the heart rate of the user. Meyerson teaches that an accelerometer sensor is able to detect a level of constant pressure, not just changes in pressure and is sensitive to changes in activity level of the user, therefore it would be obvious to one of ordinary skill in the art to employ an accelerometer as the sensor of the device taught by Jacobsen so as to render the device capable of detecting both a change in activity level of the user by measuring heart rate, and also capable of detecting a level which is sustainable and acceptable for the user as taught by Meyerson.

Claim 136 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (U.S. Patent No. 5,860,957) in view of Crivelli (U.S. Patent Application Publication No. 2003/0016262) as applied to claims 83-100, 108, 109, 119, 120, 123, 126-128, 140, 141, and 148-150 above, and further in view of Nakamura et al (U.S. Patent No. 6,564,092).

With respect to **Claim 136**: Jacobsen does not teach applying a bioactive composition attracting agent and pulling said bioactive toward said agent, or penetrating the agent with the composition. Nakamura et al teaches that ointments (attracting agent) and patches are both known in the art as carriers or formats for delivering physiologically active (i.e. bioactive) compositions transdermally. In the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency, *In re Fount* 213 USPQ 532

(CCPA 1982); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *Graver Tank & Mfg. Co. Inc. v. Linde Air Products Co.* 85 USPQ 328 (USSC 1950).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

January 30, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', written over the printed name and title.